TRAVERSE

In the first instance, Applicant submits that the restriction requirement is improper, and if maintained, should be instead a requirement for election of species. Second, Applicant submits the restriction is based on an imprecise classification, and requests reconsideration and withdrawal of the requirement. Third, Applicant requests modification of the requirement, should the Examiner maintain the requirement.

1. Restriction Between Two Species of a Generic Claim

The Examiner has effectively required restriction between two species of generic claim 21, i.e. administering a polypeptide antigen, and administering a nucleic acid that encodes an antigen.

As a preliminary matter, alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

Moreover, it has been held that an Examiner may not reject a particular claim on the basis that it represents independent and distinct inventions. *See, In Re Weber, Soder and Boksay, Supra*. The courts have ruled that the statue authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restricti n requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder*

and Boksay, *In Re Haas I* and *In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

Instead of imposing a restriction requirement on a single claim, the Office may limit initial examination to a reasonable number of species encompassed by the claim. *See*, 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See*, the MPEP at 803.02. *See also, In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application.

If the Examiner agrees that claim 21 presents a generic linking claim between Groups I and II, Applicant provisionally elects Group I as a species with traverse, subject to the following requests for withdrawal and modification.

2. Request for Withdrawal of Requirement

The Office has characterized claim 21 under:

I) Class 435, Subclass 70.1, which relates to using tissue cell culture to make a protein or polypeptide; and

II) Class 514, Subclass 44, which relates to a polynucleotide drug or composition.

Yet the claim is not drawn to the use of a tissue cell culture, nor is it drawn to a polynucleotide drug. Instead, the claim recites a method of making a harvested mammary

secretion product. Applicant respectfully submits a more accurate characterization of the claim can be, for example, one of the following Class/Subclass combinations:

a) Class 514, Subclass 2, which relates to subject matter containing a protein or its reaction product;

b) Class 530, Subclass 827, which relates to proteins from mammals or birds; or

c) Class 424, Subclass 520, which relates to compositions or products wherein the active ingredient is an animal body fluid.

With regard to claim 21, the only reference cited in the first Office Action is U.S. 5,017,372 to Hastings. This cited patent indicates a Field of Search for Classes 424, 530, and 514, which is consistent with the classification approach suggested above. Applicant submits there is no undue burden on the Office to consider Group I and II together based upon such classification. It is natural and desirable to conduct the search in connection with examination of the claims of Group I and II. In fact, simultaneous prosecution of the claims would be more efficient.

What is more, according to the Office Action, claim 21 is directed to administering a polypeptide antigen. Such a reading requires a strained interpretation of the presently claimed invention. The Examiner appears to base the requirement on the incorrect inference that Group I claims are confined to methods of making an antibody by immunizing with a polypeptide antigen. However, Group I claims do not recite a step that is limited to administration of a proteinaceous antigen. The nature of the antigen is not specified in presently pending claim 21, and may thus be, for example, a protein, a carbohydrate, a nucleic acid, or any other hapten or epitope one could think of. Therefore, the Group II claims that recite a step that includes administration of a nucleic acid encoding a polypeptide antigen are completely within the scope of independent claim 21, and should be examined with the Group I claims.

Based on the above, Applicant respectfully requests withdrawal of the requirement.

3. Request for Modification of the Requirement

Presently pending claim 21 does not recite a polypeptide antigen element. Consequently, Applicant believes that the Office Action mailed September 30, 2002 was based on a search that was not so limited. In the event the Examiner maintains the requirement, Applicant respectfully requests that going forward, Group I claims not be limited to antigens of the polypeptide type.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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CLAIMS PRESENTLY UNDER EXAMINATION

21. (Amended) A method of making a harvested mammary secretion product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal; and

harvesting the mammary secretion product from the farm-animal.

22. (Amended) The method of claim 21, wherein the hyperimmunizing step comprises administering the antigen to an airway of the farm-animal.

23. (Amended) The method of claim 22, wherein the hyperimmunizing step comprises administering the antigen intranasally to the farm-animal.

24. (Amended) The method of claim 21, wherein the mammary secretion product is milk.

25. (Amended) The method of claim 21, wherein the antibody is an IgA antibody.

26. (Amended) The method of claim 21, further comprising boosting an immune response to the antigen in the farm-animal.

27. The method of claim 26, wherein the boosting step comprises administering the antigen to an airway, a mammary gland, and/or a supramammary lymph node of the farm-animal.

28. (Amended) A method of making an antibody composition comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

deriving the antibody composition from the harvested mammary secretion product.

29. (Amended) A method of making an antigen-specific antibody, the method comprising:

hyperimmunizing a farm-animal for an antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting a mammary secretion product from the farm-animal; and

deriving the antigen-specific antibody from the harvested mammary secretion product.

30. (Amended) A method of making a medicament comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

incorporating the mammary secretion product into the medicament.

31. (Amended) A method of making a food product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen via a mucosal passage of the farm-animal;

administering the antigen to a mammary gland and/or a supramammary lymph node of the farm-animal;

harvesting the mammary secretion product from the farm-animal; and

incorporating the mammary secretion product into the food product.

32. (New) The method of claim 21, wherein the antigen is administered through administering nucleic acid encoding the antigen or functional equivalent thereof.

33. The method of claim 21, wherein the antigen is administered at least once in the supramammary lymph node.

34. The method of claim 21, wherein the antigen is administered at least twice in the supramammary lymph node.

35. The method of claim 21, wherein the farm-animal is a cow or a goat.

36. The method of claim 21, wherein the hyperimmunizing step further comprises administering an adjuvant to the farm-animal.

37. The method of claim 36, wherein the adjuvant is toxin B of *Clostridium difficile*.

38. The method of claim 21, wherein the antigen is derived from a culture of *Clostridium difficile*.

39. The method of claim 38, wherein the antigen is a protein from a *Clostridium difficile* (VPI10463) cell.

40. The method of claim 38, wherein the antigen is a *Clostridium difficile* spore.

41. The method of claim 38, wherein the antigen comprises *Clostridium difficile* Toxin A.

42. The method of claim 38, wherein the antigen comprises *Clostridium difficile* Toxin B.

43. The method of claim 38, wherein the antibody is specific for a protein of *Clostridium difficile*.

44. The method of claim 38, wherein the antibody is specific for a *Clostridium difficile* spore.

45. The method of claim 21, wherein the farm-animal is a lactating farm-animal.

46. The method of claim 21, wherein the hyperimmunizing step comprises administering the antigen via an intramucosal route selected from the group consisting of intraudder, intravaginal, intrarectal, or intranasal.

47. The method of claim 21, wherein the airway administration is achieved in the form of aerosols.

48. The method of claim 21, wherein the hyperimmunizing step comprises at least two airway administrations of the antigen.

49. The method of claim 21, wherein the hyperimmunizing step comprises at least four airway administrations of the antigen.

50. The method of claim 21, wherein the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal about 6 weeks following the hyperimmunizing step.

51. The method of claim 21, wherein the harvested mammary secretion product has an IgA titer of at least 1000 units/ml.

52. The method of claim 21, wherein the harvested mammary secretion product has an IgA titer of at least 1000 units/ml and is harvested up to about 10 weeks after the antigen is administered to the mammary gland and/or the supramammary lymph node of the farm-animal.

53. The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of at least 100 units/ml.

54. The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of at least 100 units/ml and is harvested up to about 8 weeks after the antigen is administered to the mammary gland and/or the supramammary lymph node of the farm-animal.

55. The method of claim 21, wherein the hyperimmunizing step further comprises administering the antigen intramuscularly to the farm animal.

56. The method of claim 21, wherein the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal about 3 weeks following the hyperimmunizing step.

57. The method of claim 21, wherein the harvested mammary secretion product has an IgG titer of about 130 units/ml to about 430 units/ml.

58. The method of claim 21, wherein a second hyperimmunization step is performed after the antigen is administered to the mammary gland and/or supramammary lymph node of the farm-animal.

59. The method of claim 58, wherein the antigen is administered a second time to the mammary gland and/or supramammary lymph node of the farm-animal following the second hyperimmunization step.

60. The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration has an IgG titer of at least 400 units/ml.

61. The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration has an IgA titer of at least 3500 units/ml.

62. The method of claim 59, wherein the mammary secretion product harvested after the second mammary gland and/or supramammary lymph node administration does not have a strong quarter specificity for IgA titer.

63. The method of claim 24, wherein the milk from the farm-animal comprises at least 0.5 μg/ml of antibody specific for the antigen.

64. The method of claim 24, wherein the milk from the farm-animal comprises at least 15 μg/ml of antibody specific for the antigen.

65. The method of claim 24, wherein the milk from the farm-animal comprises at least 50 μg/ml of antibody specific for the antigen.

66. The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 50 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

67. The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 100 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

68. The method of claim 24, wherein the milk from the farm-animal comprises the antibody specific for the antigen in a quantity of at least 200 percent of the average quantity of the antibody specific for the antigen that is obtainable from a colostrum of the farm-animal.

69. The method of claim 62, wherein the antibody specific for the antigen is an IgA antibody.

70. The method of claim 63, wherein the antibody specific for the antigen is an IgA antibody.

71. The method of claim 64, wherein the antibody specific for the antigen is an IgA antibody.

72. The method of claim 65, wherein the antibody specific for the antigen is an IgA antibody.

73. The method of claim 66, wherein the antibody specific for the antigen is an IgA antibody.

74. The method of claim 67, wherein the antibody specific for the antigen is an IgA antibody.

75. A method of making a harvested mammary secretion product comprising an antibody specific for an antigen, the method comprising:

hyperimmunizing a farm-animal for the antigen;

administering the antigen to a supramammary lymph node of the farm-animal; and

harvesting the mammary secretion product from the farm-animal.